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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/944,929 | 08/31/2001 | Kevin P. Baker | P2548P1C21 | 2450 |

7590 10/06/2004

BRINKS, HOFER, GILSON & LIONE
PO BOX 10395
Chicago, IL 60611-5599

EXAMINER

VOGEL, NANCY S

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1636

DATE MAILED: 10/06/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 09/944,929 | BAKER ET AL. | |
| | Examiner | Art Unit | |
| | Nancy T. Vogel | 1636 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 July 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 24-41 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 24-41 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 7/12/04 has been entered.

Claim Rejections - 35 USC § 101

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 24-41 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility.

This rejection on is maintained for the reasons made of record set forth in the previous Office action, mailed 2/12/04.

Applicants' arguments, and the declaration of Dr. Sherman Fong submitted therewith, of 7/12/04, have been considered but have not been found convincing.

Applicants have argued that since the specification discloses that the polypeptide encoded by the nucleic acids of the claims is "capable of inhibiting T-cell proliferation", this is adequate support for a "specific utility", and further, that they have disclosed a condition to be treated by the sequence of the instant application, i.e. "the immune response". Applicants further argue that one of ordinary skill in the art would "appreciate that only certain diseases involve treatment of the immune response", and present the Declaration of Sherman Fong, Ph.D. in support of this argument. Applicants further argue that Dr. Fong states that the MLR assay of the present invention identifies immune stimulants that can boost the immune system to respond to a particular antigen" and further, "the MLR assay is not a general predictor of immune response but rather is a specific assay designed to test the ability of a sample, such as an isolated nucleic acid encoding the polypeptide of SEQ ID NO:83 or an isolated nucleic acid of SEQ ID NO:82, to inhibit the drive of dendritic cells to induce T-cell proliferation" (page 5). However, these general statements fail to address the main contention of the previous Office action, which is that there is a poor correlation between in vitro results and in vivo results using the MLR assay. Applicants' further arguments regarding this matter at pages 5-7 are not found convincing, since applicants set forth several examples of particular test substances in the MLR, which correlated to in vivo results. While in these instances there may have been a correlation, it is maintained that the general teachings in the art, as evidenced by the art previously cited in the Office action of 2/12/04. One of ordinary skill in the art, in possession of these general teachings would recognize that one cannot extrapolate the utility of a compound for suppressing

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any particular immune response in vivo, from the MLR in vitro assay. Applicants also argue that one of ordinary skill in the art would "appreciate that CD4-IgG is an antibody that might be used as a negative control by blocking or preventing activation of allogenic responder cells" (page 8) and further, that "applicants disclose that cell culture media can be used as a control" (page 8), fails to address the issues raised in the previous Office action, namely, there are several controls which would be meaningful for this assay, including autologous controls, a control to determine maximum response, screening for possible HLA antibodies and growth support capabilities, and internal controls. These issues have not been addressed. Furthermore, the issue of lack of statistical analysis, or the lack of the presence of the data itself, provides further uncertainty in the evaluation of any in vitro effect of the PRO361. For the reasons set forth above, applicant's arguments have not been found convincing, and the rejection is maintained.

Claim Rejections - 35 USC § 112

Claims 24-41 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

This rejection is maintained for the reasons set forth above.

Conclusion

All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a). A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nancy T. Vogel whose telephone number is (571) 272-0780. The examiner can normally be reached on 6:30 - 3:00, Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Irem Yucel, Ph.D. can be reached on (571) 272-0781. The fax phone

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number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


TERRY MCKELVEY
PRIMARY EXAMINER